were not adequate directions for use; Section 502 (f) (2), the boxes containing the drugs bore no labeling containing warnings against use in those pathological conditions wherein use of the drug might be dangerous to health, or against unsafe dosage and methods and duration of administration; and, Section 502 (j), the drug, when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, "Two every 4 hours," was dangerous to health.

DISPOSITION: March 4, 1946. A plea of nolo contendere having been entered, the court imposed a fine of $750.

1852. Adulteration and misbranding of atropine sulfate ointment and Nepco Ammoniated Mercury Ointment, and misbranding of Nepco Ephedrine Nasal Jelly and Nepco Sulfur Ointment. U. S. v. New England Pharmaceutical Corporation. Plea of guilty. Fine, $50 on each of 5 counts; sentence suspended on count 6. (F. D. C. No. 17817. Sample Nos. 92835–F, 93003–F, 93701–F, 93703–F, 93707–F.)

INFORMATION FILED: April 12, 1946, Southern District of New York, against the New England Pharmaceutical Corporation, New York, N. Y.

ALLEGED SHIPMENT: On or about January 17 and October 23, 1944, from the State of New York into the District of Columbia and the State of New Jersey.

PRODUCT: Analyses disclosed that various tubes of the *atropine sulfate ointment* contained atropine sulfate in amounts varying from 0.46 percent to 2.60 percent; that the *nasal jelly* contained approximately 1 percent of ephedrine sulfate; that the *ammoniated mercury ointment* contained ammoniated mercury corresponding to 8.4 percent of mercury; and that the *sulfur ointment* was of U. S. P. strength.

NATURE OF CHARGE: *Atropine sulfate ointment.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, in that it was represented to contain 1 percent of atropine sulfate, whereas some of the tubes of the article contained less than 1 percent of atropine sulfate and other tubes contained more than 1 percent of atropine sulfate. Misbranding, Section 502 (a), the label statement, "Atropine Sulfate 1%," was false and misleading.

Ephedrine nasal jelly. Misbranding, Section 502 (a), the label statement, "For Head Colds, Etc., Subacute and Chronic Cases * * * used for relief of inflammatory condition of the Nose and Throat, such as Rhinitis, Laryngitis, Common Cold, Hay Fever, especially in subacute and chronic cases," were false and misleading since the article would not be an adequate treatment for head colds and other conditions suggested by the word "Etc."; it would not be an adequate treatment for subacute and chronic cases of head colds; and it would not be an adequate treatment for the relief of inflammatory conditions of the nose and throat, rhinitis, laryngitis, common colds, and hay fever, whether subacute and chronic or otherwise. Further misbranding, Section 502 (f) (2), the article contained ephedrine and its label failed to bear a warning that individuals suffering from high blood pressure, heart disease, diabetes, or thyroid trouble should not use the article except upon competent advice; and its labeling also failed to warn that frequent or continued use of the article might cause nervousness, restlessness, or sleeplessness.

Ammoniated mercury ointment. Adulteration, Section 501 (b), the article purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the official standard in that it contained more than 4.5 percent of mercury, the maximum allowed by the standard, and its difference in strength from the standard was not plainly stated, or stated at all, on its label. Misbranding, Section 502 (a), the label statements, "Ammoniated Mercury Ointment U. S. P." and "Ammoniated Mercury U. S. P. XI," were false and misleading since the article did not consist of ammoniated mercury ointment that conformed to the requirements of the Pharmacopoeia. Further misbranding, Section 502 (a), the label statement, "A stimulant and parasiticide in cutaneous eruptions, as scabies, ringworm, exzema and porrigo," was false and misleading since it represented and suggested that the article would be an adequate treatment for cutaneous eruptions such as scabies, ringworm, eczema, and porrigo, whereas it would not be an adequate treatment for those conditions; Section 502 (f) (2), the labeling of the article failed to bear a warning that application of the article to large areas of the body might cause serious mercury poisoning; and, Section 502 (j), the article, because of its content of mercury, would be dangerous to health when used in

the treatment of scabies in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, "Directions Apply with cotton or gauze on to affected parts."

Sulfur ointment. Misbranding, Section 502 (f) (1), the article was offered for the treatment of scabies, and the directions for use in such treatment, "Directions Apply directly to affected parts," appearing on the label of the article, were not adequate directions for use in the treatment of scabies.

DISPOSITION: April 18, 1946. A plea of guilty having been entered on behalf of the defendant, the court imposed a fine of $50 on each of counts 1 through 5 of the information and suspended sentence on count 6, which related to the misbranding of the *sulfur ointment.*

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

1853. Adulteration and misbranding of Bactratycin Antibiotic Ointment. U. S. v. 32 Jars of Bactratycin Antibiotic Ointment. Default decree of condemnation and destruction. (F. D. C. No. 17335. Sample No. 6350–H.)

LIBEL FILED: September 11, 1945, Southern District of New York.

ALLEGED SHIPMENT: On or about July 26, 1945, by the Wallace Laboratories, Inc., from New Brunswick, N. J.

PRODUCT: 32 jars of *Bactratycin Antibiotic Ointment* at New York, N. Y.

NATURE OF CHARGE: Section 505, the article was a new drug in that its composition was such that, as a result of investigations to determine its safety for use, it had become recognized as safe for use under the conditions prescribed, recommended, and suggested in its labeling, but it had not, otherwise than in such investigations, been used to a material extent or for a material time under such condtions; it was not, prior to June 25, 1938, subject to the Food & Drugs Act of 1906; and no application had been filed pursuant to the law which was effective with respect to the article.

Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented by the following statements to possess, since the article contained no significant proportion, if any, of gramicidin and therefore no significant proportion, if any, of tyrothricin: (Labels) "Bactratycin Antibiotic Ointment containing Tyrothricin Each gram contains 0.30 mg. Tyrothricin (gramicidin and tyrocidin)"; and (enclosed circular) "Ointment containing Tyrothricin Bactratycin * * * utilizing the gram-positive bacteria-killing properties of tyrothricin * * * employing both fractions of tyrothricin (gramicidin * * *) Activity: Tyrothricin, the active ingredient in Bactratycin * * * Potency: Each gram of Bactratycin contains 0.30 mg. tyrothricin."

Misbranding, Section 502 (a), certain statements in the circular enclosed in each package of the article were false and misleading since they represented, suggested, and implied that the article contained a significant proportion of gramicidin; that it exhibited an appreciable antibiotic activity such as would characterize a gramicidin-containing ointment; and that the article would be effective in the treatment of impetigo, pustular dermatitis, infective dermatitis, various types of ulcers, abscesses, infected wounds, and similar surface lesions caused or complicated by streptococci, staphylococci, pneumococci, or other gram-positive organisms. The article contained no significant proportion, if any, of gramicidin; it exhibited no appreciable antibiotic activity such as would characterize a gramicidin-containing ointment; and it would not be effective in the treatment of the conditions stated.

DISPOSITION: September 13, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

1854. Action to enjoin and restrain the misbranding of drugs in interstate commerce. U. S. v. I. James Hendelberg (Southeast Pharmacy). Injunction granted. (Inj. No. 138.)

COMPLAINT FILED: March 29, 1946, District of Columbia, against I. James Hendelberg, trading as the Southeast Pharmacy, Washington, D. C.

*See also Nos. 1851, 1852.